DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 17 1986

Re: Cefotan
Docket No. 86E-0098

MAR 20 1986

GROUP 120

Mr. Charles E. Van Horn
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term restoration for U.S. Patent No. 4,263,432, filed by Yamanouchi Pharmaceutical Co., Ltd., under the patent term restoration provisions of 35 U.S.C. 156. The human drug product claimed by the patent is Cefotan (cefotetan disodium), New Drug Application (NDA) 50-588.

A review of the Food and Drug Administration's official records indicates that Cefotan, the product identified in the patent term restoration application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that NDA 50-588 represents the first permitted commercial marketing or use of the active ingredient, cefotetan disodium. The NDA was approved on December 27, 1985 which makes the submission of the patent term restoration application on February 21, 1985 timely within 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term restoration, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Rosemary M. Miano, Esq.
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